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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,221	10/17/2005	Tetsuya Yano	03500.018109	9077

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EXAMINER	
LILLING, HERBERT J	
ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,221	YANO ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-17-05;11-30-06; [tot 9 pgs]*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of an election response filed December 27, 2007 for this application for this Application which is a 371 of PCT/JP04/06296 filed April 30, 2004 which claims benefit to JP 2003-127503 filed May 02, 2003.

2. Claims 1-20 are pending in this application.

3. Applicant has elected without traverse Invention I, claims 1-6 and 20.

Claim 7-19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 27, 2007.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. In accordance with this Tech Center Policy based on above restriction containing product claims and process claims, this Examiner will rejoin any non-elected

process claims upon the election of a product claim which is subsequently is found allowable in view of the following guidelines:

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims **directed to the product**, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, **Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1-6 and 20 are rejected under 35 U.S.C. 102(b/e) as being anticipated by Gray et al U.S. 6,167,313 which reference teaches the following:

"**Brief Summary Text** Preferably, the magnetic material is bound in a matrix material which does not adversely effect the hysteresis or eddy current heating properties of the magnetic particles. The non-toxic binder or matrix material may comprise any of the suitable non-toxic materials which are well known in the microencapsulation art. Suitable materials include, for example, proteins, polymeric resins such as styrene-divinylbenzene, biopol, albumin, chitoxan etc.

Detailed Description Text A number of different methods may be used to **prepare the microcapsules** using a diverse range of matrix materials and manufacturing techniques. In one preferred form of this invention, the microcapsules contain cobalt treated .gamma.Fe.sub.2 O.sub.3 particles as the ferromagnetic material, bound together using a **Biopol matrix (a copolymer of (R)-3-hydroxybutyric acid and (R)-3-hydroxyvaleric acid).** Using this matrix, magnetic microcapsules in a density range of 1.8-2.2 g/cm.sup.3 and in a size range 20-50 microns can be obtained.

In an alternative method, ferromagnetic particles may be added to a solution containing Biopol in dichloromethane. The mixture is preferably then dropped into a beaker containing poly-vinyl alcohol or the like while being mixed with a homogenising mixer. The mixture should then be left to slowly mix for a suitable period of time to allow the dichloromethane to evaporate. Microcapsules thus formed, may then be washed and size fractionated.

.gamma.Fe.sub.2 O.sub.3 particles having a maximum MHE of 1.05.times.10.sup.-7 J.m./A.g, when the field strength was 47.1 kA/m were obtained from Bayer Chemicals. 1 g of .gamma.Fe.sub.2 O.sub.3 particles was thoroughly mixed with a 6 ml solution containing 15% Biopol (Fluka Chemie, Switzerland) in dichloromethane. This mixture was then dropped into a beaker containing 150 ml of 0.25% poly-vinyl alcohol (2.5 g of PVA 87-89% hydrolyzed, MW 124,000-186,000 dissolved in 1 Liter of water) while being mixed with a homogenising mixer set at 3900-4000 rpm. The mixture was then left mixing for 10 minutes after which it was left to mix very slowly for 60 minutes to allow all the dichloromethane to evaporate."

7. Claims 1-6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gomez-Lopera et al, or Hafeli et al., Gray et al U.S. 6,167,313 each

alone or further in view of each other or Shi, Yanggu, et al. 20020064844. Published May 02, 2002.

Gomez-Lopera et al.:
teaches biodegradable polymer composites containing magnetic particles encapsulated in the polymeric shell. The polymeric shell is a polylactide also abbreviated as PLA [polylactic acid], which is prepared by emulsion polymerization but does not disclose a biodegradable PHA polymeric shell.

Hafeli et al., teaches microspheres containing magnetic components which includes magnetite and or 90Y radioactive components with PLA but does not disclose PHA shells.

Gray et al. recites:

"In one preferred form of this invention, the microcapsules contain cobalt treated .gamma.Fe.sub.2 O.sub.3 particles as the ferromagnetic material, bound together using a Biopol matrix (a copolymer of (R)-3-hydroxybutyric acid and (R)-3-hydroxyvaleric acid). Using this matrix, magnetic microcapsules in a density range of 1.8-2.2 g/cm.sup.3 and in a size range 20-50 microns can be obtained."

Shi, Yanggu, et al teaches the following:

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In view of the prior art, it would have been prima facie obvious to select the magnetic particles of Gray et al as recited:

"microcapsules contain cobalt treated .gamma.Fe.sub.2 O.sub.3 particles as the ferromagnetic material, bound together using a Biopol matrix (a copolymer of (R)-3-hydroxybutyric acid and (R)-3-hydroxyvaleric acid). Using this matrix, magnetic microcapsules in a density range of 1.8-2.2 g/cm.sup.3 and in a size range 20-50 microns can be obtained."; to prepare a microcapsule using a PHA as indicated "copolymer of (R)-3-hydroxybutyric acid and (R)-3-hydroxyvaleric acid" as the shell which renders the claims prima facie obvious.

In addition, both Gomez-Lopera et al., and Hafeli et al., teach PLA polymeric shells which reference to Gomer-Lopera is drawn to

"Hence, the main aim of the present contribution is to explore the possibilities of preparing mixed particles, **susceptible to external magnetic fields but covered with a shell of biodegradable polymer.**"

Thus, it would have been prima facie obvious to substitute the polymer of Shi et al in view of the following:

> "**Examples of biodegradable polymers** which can be used in the formulation of compositions of the invention include, but are not limited to, **polylactides,** ....., **polyhydroxybutyrates**, **polyhydroxyvalerates,**.. and copolymers, terpolymers, or combinations or mixtures of the above materials.

> Detail Description Paragraph:
> [0896] It is also preferred that the solvent for the biodegradable polymer be non-toxic, water miscible, and otherwise biocompatible. Examples of such solvents include, but are not limited to, N-methyl-2-pyrrolidone, 2-pyrrolidone, C2 to C6 alkanols, C1 to C15 alchohols, dils, triols, and tetraols such as ethanol, glycerine propylene glycol, butanol; C3 to C15 alkyl ketones such as acetone, diethyl ketone and methyl ethyl ketone; C3 to C15 esters such as methyl acetate, ethyl acetate, ethyl lactate; alkyl ketones such as methyl ethyl ketone, C1 to C15 amides such as dimethylformamide, dimethylacetamide and caprolactam; C3 to C20 ethers such as tetrahydrofuran, or solketal; tweens, triacetin, propylene carbonate, decylmethylsulfoxide, dimethyl sulfoxide, oleic acid, 1-dodecylazacycloheptan-2-one, Other preferred solvents are benzyl alchohol, benzyl benzoate, dipropylene glycol, tributyrin, ethyl oleate, glycerin, glycofural, isopropyl myristate, isopropyl palmitate, oleic acid, polyethylene glycol, propylene carbonate, and triethyl citrate. The most preferred solvents are N-methyl-2-pyrrolidone, 2-pyrrolidone, dimethyl sulfoxide, triacetin,

and propylene carbonate because of the solvating ability and their compatibility.

Detail Description Paragraph:
[0897] Additionally, formulations comprising compositions of the invention and a biodegradable polymer may also include release-rate modification agents and/or pore-forming agents. Examples of release-rate modification agents include, but are not limited to, fatty acids, triglycerides, other like hydrophobic compounds, organic solvents, plasticizing compounds and hydrophilic compounds. Suitable release rate modification agents include, for example, esters of mono-, di-, and tricarboxylic acids, such as 2-ethoxyethyl acetate, methyl acetate, ethyl acetate, diethyl phthalate, dimethyl phthalate, dibutyl phthalate, dimethyl adipate, dimethyl succinate, dimethyl oxalate, dimethyl citrate, triethyl citrate, acetyl tributyl citrate, acetyl triethyl citrate, glycerol triacetate, di(n-butyl) sebecate, and the like; polyhydroxy alcohols, such as propylene glycol, polyethylene glycol, glycerin, sorbitol, and the like; fatty acids; triesters of glycerol, such as triglycerides, epoxidized soybean oil, and other epoxidized vegetable oils; sterols, such as cholesterol; alcohols, such as C.sub.6-C.sub.12 alkanols, 2-ethoxyethanol, and the like. The release rate modification agent may be used singly or in combination with other such agents. Suitable combinations of release rate modification agents include, but are not limited to, glycerin/propylene glycol, sorbitol/glycerine, ethylene oxide/propylene oxide, butylene glycol/adipic acid, and the like. Preferred release rate modification agents include, but are not limited to, dimethyl citrate, triethyl citrate, ethyl heptanoate, glycerin, and hexanediol. Suitable pore-forming agents that may be used in the polymer composition include, but are not limited to, sugars such as sucrose and dextrose, salts such as sodium chloride and sodium carbonate, polymers such as hydroxylpropylcellulose, carboxymethylcellulose, polyethylene glycol, and polyvinylpyrrolidone. Solid crystals that will provide a defined pore size, such as salt or sugar, are preferred."

Furthermore in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007). Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention, that invention may still be found obvious based on the above e supported by appropriate facts and reasoning, and explanation for the obviousness of the claimed subject matter which factual findings provide guidance that one of ordinary skilled in the art would have

reasonably have expectations that the references alone or further in view of each render the claimed subject matter unpatentable based on obviousness.

8. **No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
January 11, 2008

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